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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,783	05/16/2000	NEIL P. DESAI	VPHAR1460-2	2878

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/10/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/446,783

Applicant(s)

DESAI ET AL.

Examiner

Michael G. Hartley

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35, 46-67 and 70-121 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 29-35, 46-67 and 70-121 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 29 and 30, drawn to a method of administering a taxane using hardware, e.g., tubing, bottles, syringes, etc.

Group 2, claim(s) 31, drawn to a method of administering a taxane without the use of a filter.

Group 3, claim(s) 32-34, drawn to a method of administering a taxane by administering a complete dose in a volume of less than 250ml.

Group 4, claim(s) 35 and 76-78 drawn to a method of administering a taxane at a rate between 6-30 mg/ml²/min over 1 hr. or less.

Group 5, claim(s) 46, 47, 79 and 80, drawn to a dry powder comprising taxane nanoparticles which are free of surfactant.

Group 6, claim(s) 48, drawn to a frozen taxane formulation.

Group 7, claim(s) 49-51, 81 and 94-97 drawn to a liquid formulation of taxane comprising water and a taxane which is stable for 3 days.

Group 8, claim(s) 52, 86, 87, 98 and 99 drawn to a drug formulation for inhalation or oral administration comprising at least one protein and drug microparticles.

Group 9, claim(s) 53-60 and 62-64 drawn to a method of making nanoparticles containing an active agent and a surfactant.

Group 10, claim(s) 61, 65 and 100 drawn to a method of making nanoparticles containing an active agent without a surfactant.

Group 11, claim(s) 66, drawn to a taxane powder free of surfactant.

Group 12, claim(s) 67, drawn to a taxane powder free of cremaphor.

Group 13, claim(s) 70, drawn to a lyophilized taxane.

Group 14, claim(s) 71, drawn to taxane particles.

Group 15, claim(s) 72-75 and 101-108 drawn to a dry powder comprising a protein.

Group 16, claim(s) 82-85, drawn to a method of administering a taxane at a concentration of 2mg/ml.

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Group 17, claim(s) 88-91 and 109-114, drawn to an article of manufacture comprising a sealed vial and at least one protein and drug microparticles.

Group 18, claim(s) 92 and 115-118, drawn to a formulation of paclitaxel wherein the AUC is less than for taxol.

Group 19, claim(s), 93 and 119-121 drawn to paclitaxel having a higher half-life than taxol.

The inventions listed as Groups 1-19 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the groups have different inventive general inventive concepts as can be seen by what the grouped invention is drawn to as set forth above, e.g., different methods of administering a taxol, microparticles, formulations, methods of making which are different, paxlitaxel, etc.

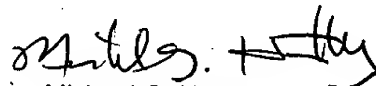
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
April 4, 2003.